Rational Pharmaceutical Management Plus
Introduction of Antiretroviral Therapy in Mombasa, Kenya: Trip Report of Technical Assistance to Support Program, November 17 to December 4, 2003

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Contents

Acronyms

ADR	adverse drug reaction
AHFS	American Hospital Formulary Service
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral [drugs]
CCC	Comprehensive Care Centre [CPGH]
CPGH	Coast Provincial General Hospital
CPK	creatine phosphokinase
DAART	Directly Administered Antiretroviral Therapy
DUR	drug utilization review
FHI	Family Health International
ELISA	enzyme-linked immunosorbent assay
GOK	Government of Kenya
HDL	high-density lipoprotein
HIV	human immunodeficiency virus
ICRH	International Centre for Reproductive Health
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
K	Potassium
KEMRI	Kenya Medical Research Institute
LDL	low-density lipoprotein
MIS	management information system
MOH	Ministry of Health [Kenya]
MSH	Management Sciences for Health
Na	Sodium
NASCOP	National AIDS/ and Sexually Transmitted Diseases Control Programme [Kenya]
OHA	[USAID] Office of HIV/AIDS
OPD	out patient department [CPGH]
PBMC	peripheral blood mononuclear cells
PEP	post exposure prophylaxis [for HIV]
PMO	Provincial Medical Officer [Coast Province]
QA	quality assurance
QC	quality control
RDU	rational drug use
RPM	Rational Pharmaceutical Management Plus [Program]
SO4	[USAID/Washington] fourth strategic objective
SOP	standard operating procedure
TAP	technical assistance partners [IMPACT/RPM Plus/Horizons]
USAID	U.S. Agency for International Development
U.S.HHS	U.S. Department of Health and Human Services
VCT	voluntary counseling and testing [HIV]
WHO	World Health Organisation

Background

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program has received funding from the United States Agency for International Development (USAID) under USAID's fourth strategic objective (SO4) to collaborate with Family Health International (FHI)/Implementing AIDS Prevention and Care Project (IMPACT) and Population Council/Horizons to support the Government of Kenya (GOK), USAID/Kenya, USAID/Washington and local partners to introduce antiretroviral therapy (ART) for selected communities of HIV infected individuals in Mombasa District of Kenya's Coast Province, as part of a comprehensive package of prevention, care and treatment. The Mombasa ART Program will provide valuable implementation and operations research on how to safely and effectively deliver antiretrovirals (ARVs) and how to build capacity to expand access to treatment. The dissemination of assessment and implementation results, tools, and lessons learned is an important component of this activity.

In September 2001, RPM Plus accompanied representatives from USAID/Office of HIV/AIDS (OHA), USAID/Kenya, to meetings with the Minister of Health, the Permanent Secretary for Health, the Minister of Public Health, the Director of Medical Services and the Chairman of the Pharmacy and Poisons Board of Kenya to discuss the Mombasa ART Program, drug registration, procurement and other drug management issues. RPM Plus also accompanied representatives from OHA, Kenya Mission, IMPACT, and Horizons on a site visit to Mombasa where the team met with the Provincial Medical Officer (PMO) for Mombasa, the Chief Administrator and Chief Pathologist at Coast Provincial General Hospital (CPGH), and local partners.

In April 2002, RPM Plus along with FHI/IMPACT and Horizons participated in a workshop in Mombasa with local partners and GOK Ministry of Health (MOH) to finalize the proposal and to draw up a timeline for the assessment.

In September 2002, RPM Plus conducted an assessment of the capacity of the pharmaceutical management system and laboratory services to support the introduction of ART in 4 sites in Mombasa, in addition to assessing current access to and use of ARVs in Mombasa city.

In November 2002, RPM Plus presented the results of a pharmaceutical management system and laboratory services assessment conducted from September 5 to 29, 2002 at a meeting of stakeholders. Invited participants included members of the Steering Committee and also other key stakeholders and partners, including representatives from the four sites.

In January 2003, RPM Plus met with the implementation team and key partners at each of the four sites to present and solicit feedback on the results of the pharmaceutical management system and laboratory services assessment. In addition, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at CPGH to select and prioritize options and recommendations to develop an implementation plan in preparation for the start up of the Mombasa ART Program.

Capacity building activities at CPGH began in January 2003 and an initial multidisciplinary training was held at the end of March 2003. CPGH was the first of the four proposed

implementing sites to begin delivering ART – ARVs were dispensed to the first patient on June 3, 2003. RPM Plus has been providing ongoing technical assistance to CPGH to support implementation of strategies to strengthen the pharmaceutical management system and laboratory services to support the start up and roll out of the ART Program in addition to working with the other sites to prepare for the introduction of ART.

In October 2003, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at Port Reitz District Hospital to select and prioritize options and recommendations to develop an implementation plan in preparation for roll out of the ART Program to this second site.

Purpose of Trip

Ms. Helena Walkowiak traveled to Mombasa, Kenya from November 17 to December 4, 2003 to conduct a review of the Mombasa ART Program six months after the introduction of ART at CPGH in collaboration with FHI/IMPACT and Horizons. RPM Plus focused on the technical issues for the pharmaceutical management system and laboratory, FHI/IMPACT on clinical services and overall implementation, and Horizons on operations research. In addition, Ms. Walkowiak provided site-specific support for the implementation of the ART Program in Mombasa.

Scope of Work

Scope of work for Ms. Helena Walkowiak

1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.
2. Work with FHI/IMPACT and Population Council/Horizons to conduct a six month review of the Mombasa ART Program. RPM Plus will focus on the technical issues for the pharmaceutical management system and laboratory services to collect information on progress made, lessons learned, quality of services provided and to plan next steps.
3. Work with Mrs Jedida Wachira, RPM Plus Senior Program Associate to set up the RPM Plus office in Mombasa and to provide a briefing and handover management of Mombasa-based activities.
4. Work with pharmacy and administrative staff to review the testing of the Standard Operating Procedure (SOP) for the Internal Audit; finalise and revise SOP based on the results.
5. Meet with the Scientific Committee to decide on policy issues for the operationalising of the Adverse Drug reaction (ADR) monitoring and reporting system
6. Present the Pharmacy and Laboratory SOPs to the Scientific Committee for review and approval
7. Meet with other key stakeholders, and local partners within the Kenyan Government, Ministry of Health, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate.

Activities

1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.

On December 5, 2003, Ms. Walkowiak, Dr Michael Thuo, the Regional Technical Advisor for RPM Plus and Mrs Jedida Wachira, RPM Plus Senior Program Associate met and debriefed Cheryl Sönnichsen on RPM Plus activities during the visit. Ms. Sönnichsen asked Ms. Walkowiak to provide an initial written summary of findings from the review conducted by RPM Plus of the pharmaceutical management systems and the laboratory services for USAID meetings scheduled for December 8. The summary was emailed to Ms. Sönnichsen on December 6, 2003.

2. Work with FHI/IMPACT and Population Council/Horizons to conduct a six month review of the Mombasa ART Program. RPM Plus will focus on the technical issues for the pharmaceutical management system and laboratory services to collect information on progress made, lessons learned, quality of services provided and to plan next steps.

RPM Plus worked with staff from the sites in a collaborative process to identify areas to be covered in the review, persons to be interviewed and mechanisms of disseminating the results. The review was conducted from November 24-28, 2003.

The overall objectives of the six month review of the Mombasa ART Program were to:

1. Assess the implementation of activities in the context of program objectives
2. Gain insights into the process of starting-up an ART program in a resource constrained setting, and
3. Gather information for documentation of the start-up process, lessons learned and to develop recommendations for ART program start-up and scale-up.

The main findings for CPGH were presented to the CPGH Management Team, pharmacy and laboratory staff at meetings held December 3 to 4, 2003. Feedback and comments were invited at these meetings and were incorporated into the report of the review *Antiretroviral Therapy Program Mombasa, Kenya. Report on the Six Month Program Review Conducted in November 2003: Pharmaceutical Management System and Laboratory Services.* The executive summary of the report is included as Annex 1.

3. Work with Mrs Jedida Wachira, the RPM Plus Senior Program Associate to set up the RPM Plus office in Mombasa and to provide a briefing and handover management of Mombasa-based activities.

Mrs Jedida Wachira was appointed as RPM Plus Senior Program Associate to be based in Mombasa to support the ART Program in October 2003. Ms. Walkowiak introduced Mrs Wachira to the technical partners and to staff at each of the four sites during this visit. FHI invited Mrs Wachira to set up a base in the FHI office at Sheetal Plaza in Mombasa. Mrs Wachira was also introduced to Ms. Sönnichsen at USAID/Kenya Mission during this visit.

4. Work with pharmacy and administrative staff to review the testing of the SOP for the Internal Audit; finalise and revise SOP based on the results.

Ms Walkowiak and Mrs Wachira met with Dr Achola, the Chairman of CPGH Quality Committee to review the testing of the SOP for internal auditing of the ART program. Dr Achola reported that the audit committee had not yet been appointed and therefore the SOP had not as yet been tested. Dr Achola informed RPM Plus that she would follow up with Dr Shikely, CPGH Chief Administrator, on the appointment of the audit committee on her return from travel. The audit committee should be able to test the SOP in January 2004.

5. Meet with the Scientific Committee to decide on policy issues for the operationalising of the ADR monitoring and reporting system

On December 4, 2003 the Scientific Committee met at CPGH to decide on policy issues for operationalising the ADR monitoring and reporting system. Dr Olwande, pharmacist at CPGH, led the meeting to review the SOP for reporting and monitoring ADRs and the reporting form. The next step is that RPM Plus will revise the SOP for review and testing.

6. Present the Pharmacy and Laboratory SOPs to the Scientific Committee for review and approval

The CPGH Pharmacy and Laboratory SOPs were presented to the Scientific Committee at the meeting on December 4, 2003. Dr Mandaliyia, Chairman of the Scientific Committee asked members of the committee to forward comments to him by the first week in January 2004. The next steps would be to review the SOPs which would then be forwarded to CPGH Management Committee for final review and approval.

7. Meet with other key stakeholders, and local partners within the Kenyan Government, Ministry of Health, other cooperating agencies and partners to inform implementation of the ART Intervention Program, as appropriate.

Meeting with CPGH Training Officer on November 18, 2003

Ms Walkowiak and Mrs Wachira met with the CPGH training officer to discuss repeating the initial training for new staff at the four sites or staff that missed the training conducted in April 2003 – tentative dates were set for early in 2004. It was also agreed that the ongoing training would begin in February 2004 – cadres interviewed at CPGH had agreed that lunchtime training for one hour once a month provided the best option for allowing staff to attend.

Meeting with FHI to discuss ARV Procurement Issues on December 1, 2003

Ms Walkowiak, Dr Thuo and Mrs Wachira met with FHI/IMPACT - Dr Adungosi, Ruth Odindo, John McWilliam and FHI consultant Mr Darsi Lotay to discuss procurement issues with a particular focus on streamlining the process for ordering supplies of ARVs, returning stock supplied in error, assuring acceptable shelf life on delivery and exchanging short dated stock. RPM Plus assisted CPGH Pharmacy to quantify requirements for the third order to be placed using USAID funding since the start up of the program.

CPGH Eligibility Committee Meeting on November 20, 2003

Ms Walkowiak attended the weekly meeting to review eligibility of new patients for the program.

A full report of progress to date on the Mombasa ART Program is provided in Annex 2: *Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance November 17 to December 4, 2003*. This report was prepared for the PMO and for staff at the four implementing sites.

Collaborators and Partners

USAID

Cheryl Sönnichsen, USAID/Kenya

FHI

Mr John McWilliam, FHI/Nairobi
Dr John Adungosi, FHI/Mombasa
Darsi Lotay, FHI Consultant
Ruth Odindo, FHI Mombasa
Lydia Odongo, FHI/Nairobi

Population Council/International Centre for Reproductive Health (ICRH)

Scott Geibel, Population Council/Nairobi
Dr Mark Hawken, ICRH/Mombasa
Susan Kaai, Population Council/Nairobi
Mr Paul Munyao, ICRH/Mombasa
Dr. Avina Sarna, Population Council/Delhi

ART Program Scientific Committee

Dr Mandaliyia (Chairman)

Site staff

CPGH Management and Implementation Team
Port Reitz District Hospital Management and Implementation Team
Bomu Medical Centre, Management and Implementation Team
Magongo Municipal Clinic Implementation Team

Adjustments to Planned Activities and/or Additional Activities

It was not possible to finalize the CPGH SOP for the internal audit as the audit committee had not yet been appointed.

Next Steps

1. The next steps following on from the six month review are:

   - *Dissemination of Findings*
     The report of the review will be disseminated to MOH, USAID, ART Program sites, stakeholders and technical assistance partners. In addition, the technical assistance partners have been requested by CPGH to assist site staff to develop PowerPoint presentations and pamphlets that summarize the key findings for dissemination by CPGH at conferences and to visitors.
   - *Review and Update Implementation Plans for CPGH Pharmaceutical Management System and Laboratory Services*
     The technical assistance partners will work with site staff and stakeholders to review and update the implementation plans as necessary based on the findings identified.
   - *Review Findings with Port Reitz District Hospital, Bomu Medical Centre and Magongo Clinic*
     The findings will be reviewed with ART implementation teams from the three new sites to identify how implementation of the ART Program can benefit from the lessons learned from CPGH experience to date.
   - *Plan for Ongoing Monitoring and Evaluation of the Mombasa ART Program*
     The technical assistance partners will work with MOH, USAID, the implementing sites and other key stakeholders to plan for ongoing monitoring of the program and periodic evaluations.

2. The final report of the RPM Plus assessment will be finalized and disseminated by end of April, 2004.

3. RPM Plus will work in collaboration with USAID/OHA, USAID/Kenya, partner cooperating agencies, the local government and local partners, to provide technical assistance to strengthen the pharmaceutical management system and the laboratory services at CPGH and Port Reitz District Hospital to support the introduction of ART as agreed in the implementation plans. The next steps for this are set out in Annex 2.

4. RPM Plus will support CPGH to finalise and approve SOPs developed for the ART Program
   - RPM Plus will work with pharmacy and administrative staff to review the testing of the CPGH SOP for the internal audit in January 2004.
   - The SOP for ADR monitoring and reporting system will be tested by CPGH and revised by RPM Plus early in 2004.

5. Next steps for rolling out the Mombasa ART program are for RPM Plus and FHI to draft the service delivery, pharmacy and laboratory implementation plans for review and approval by the management team at Bomu Medical Centre.

6. IMPACT and RPM Plus will work with the sites to develop an ongoing training plan and map out the curricula. The curricula will be shared with the technical assistance partners for

comments to identify overlaps and to merge activities where possible. The ongoing training will commence in February 2004.

Annex 1. Executive summary from *Antiretroviral Therapy Program Mombasa, Kenya. Report on the Six Month Program Review Conducted in November 2003: Pharmaceutical Management System and Laboratory Services.*

Executive Summary:

The United States Agency for International Development (USAID) is providing support to the Government of Kenya's (GOK) Ministry of Health (MOH) to introduce antiretroviral therapy (ART) into the existing health care system of four facilities in the Mombasa District of Kenya's Coast Province as part of a package of comprehensive HIV/AIDS prevention, care and treatment. Coast Provincial General Hospital (CPGH) is the first of the four proposed implementing sites to begin delivering ART – antiretroviral drugs (ARVs) were dispensed to the first patient on June 3, 2003. It is expected that two more sites, Port Reitz District Hospital and Bomu Medical Centre (Mkomani Clinic Society) will begin providing ART in the early part of 2004 with roll out to Magongo Municipal Clinic later in 2004.

In November 2003, the USAID-funded technical assistance partners - Family Health International (FHI)/Implementing AIDS Prevention and Care Project (IMPACT), Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus Program (RPM Plus) and Population Council/Horizons Program conducted a review of the Mombasa ART Program six months after the introduction of ART at CPGH. This table summaries achievements, challenges and lessons learned for the pharmaceutical management systems and the laboratory services identified from the review conducted by RPM Plus in collaboration with site staff. This report is complementary to the reports prepared by FHI/IMPACT on clinical services and overall implementation and by Horizons on operations research. A full report of findings is contained in the body of this report.

Six Month Program Review: Pharmaceutical Management System		
Topics	**Achievements**	**Challenges**
Collaboration and Partnerships	Collaborative and inclusive approach to planning and implementation has built commitment and ownership	The "push to start" by the technical assistance partners compromised the quality of infrastructure renovations at CPGH Pharmacy
Implementation Planning Process	Implementation planning process reported to have been extremely valuable: o Built ownership and allowed staff to contribute o Created a "vision" of the goal o Helped staff to understand the roles of all the different professionals, built trust and created the "ART Team" o Result was a plan with clearly defined and agreed roles and responsibilities and a timeline for implementation	Process needs to be more inclusive with debriefings on decisions made to pharmacy staff that cannot attend

Six Month Program Review: Pharmaceutical Management System		
Topics	**Achievements**	**Challenges**
Capacity of the Pharmaceutical Management System to Support the ART Program		
1. Program Management and Linkages	ART Program is integrated into existing CPGH pharmacy systems to support program expansion and for sustainability; integration allows pharmacy to function as one unit Formal mechanisms exist and reported to work well to communicate pharmacy issues on the ART Program to CPGH management	Formal mechanism for communicating and addressing management issues across CPGH departments supporting ART needed
2. Policies and Procedures	ART management guidelines and drug information books seen to be available at CPGH Pharmacy. Draft Standard Operating Procedures (SOPs) that build on existing GOK systems and forms developed and tested for CPGH ART Program	Need a feasible and sustainable mechanism for keeping staff up to date with latest research and developments in ART Infrequency of Scientific Meetings holding up approval of SOPs CPGH policies need to be developed for emergency supply of ARVs
3. Infrastructure	Renovations completed in CPGH pharmacy include the installation of air conditioner, refrigerator and cupboards in ARV bulk store, cupboards and the medication counselling booths in the out patient pharmacy Booths have improved confidentiality of medication counselling	Poor workmanship of the ARV bulk store cupboards and shelves and unwelcoming appearance of booths need to be addressed Air conditioner has broken down twice since installation Booths reported to interrupt patient flow
4. Human Resources	CPGH pharmacy staff are committed to making the ART Program succeed ART Program has had a "moderate" impact on CPGH workload to date The key role of the pharmacist in promoting the safe and rational use of ARVs recognized at CPGH	Lack of financial compensation or other incentives reported as demotivating factors Need to train all CPGH pharmacy staff to support scale up and to compensate for transfers

Six Month Program Review: Pharmaceutical Management System		
Topics	**Achievements**	**Challenges**
Human Resources (continued)	Multidisciplinary structure of initial training encouraged team building and helped to understand each discipline's role in ART program ART trained staff feel confident in their skills and knowledge to train others in selected topics including dispensing, medication counselling and mechanisms of action of ARVs	Initial training had too much material for the time allotted Regular ongoing training needs to start Two out of a total of eight ART trained pharmacy staff from all the sites have since been transferred ART trained staff need to develop their training and presentation skills to train others. Need more hands on experience to train in topics such as adverse drug reactions (ADRs)
5. Procurement and Inventory Management	Procurement of USAID-funded ARVs by FHI/IMPACT and ARV delivery to CPGH is now relatively smooth System to track and exchange short-dated ARV stock working well	Quantification of ARVs has been complex due to large fluctuations in the rate of scale up and characteristics of new patients entering the program. Short dated stock and unpredictable lead times have added to the complexity CPGH needs a computer and software to assist with ARV quantification "Room" temperature in Mombasa routinely exceeds recommended temperature of $25^{O}C$ for several ARVs. Non-air conditioned storage at dispensing and Directly Administered Antiretroviral Therapy (DAART) adherence study sites must be kept to a minimum
6. Rational Drug Use	No forgeries or ART prescribing by ineligible practitioners reported to date at CPGH. Prescriptions other than post exposure prophylaxis (PEP) reported to follow Scientific Committee guidelines No problems reported with dispensing of ARVs; labels and bottles/cartons are supplied by Horizons	Procurement of indinavir capsules for PEP is pending Operationalising the ADR Monitoring and Reporting System has been delayed by the infrequency of Scientific Committee meetings Long term strategy for procuring bottles/cartons and printing labels needs to be identified

Six Month Program Review: Pharmaceutical Management System		
Topics	**Achievements**	**Challenges**
Rational Drug Use (continued)	Confidentiality of booths and training on the role of medication counselling in improving adherence has motivated staff to improve quality of medication counselling for all patients	Inpatients do not always receive their ARVs at the designated times Patient flow needs to be improved at the outpatient pharmacy
7. Drug Management Information Systems and Monitoring and Evaluation	Record keeping instruments including bin cards, forms and registers mainly adapted from existing GOK documents were reported to be working well by CPGH pharmacy staff	Draft data reporting tools need to be tested and feedback reports to be developed Operationalising of the internal audit is pending the appointment of the Audit Committee
8. DAART Study	Prepacking for the DAART study is proceeding smoothly Communication channels to address problems are working well	CPGH will need a list of patient expected to collect refills each week from Horizons as the numbers increase in order to prepare the prepacks in advance Full briefing on the DAART study needed for all CPGH Pharmacy staff
Scaling Up		
Needs for scaling up the ART Program at CPGH	o All CPGH Pharmacy staff need to be trained to support scale up to low hundreds o More staff may be needed to support prepacking for DAART study as numbers increase o Increase in staff will be needed to support scale up into mid-hundreds o Larger temperature controlled storage area	
Needs to support roll out to other three sites	o Strong referral system including transfer of pharmacy patient records o CPGH will need regular consumption figures from other sites to quantify requirements	
Lessons Learned and CPGH Recommendations for Other Sites		
Commitment	o Be committed: Staffing levels are important but look at the level of commitment to solve problems and to make the ART Program a success	
Planning	o Understand your site; identify strengths and weaknesses o Collaboratively develop a plan with clearly defined and agreed roles and responsibilities with a schedule to implement o Involve different disciplines and cadres to build trust and to understand roles o Have a clearly identified leader or manager for the ART Program at each site	

Six Month Program Review: Pharmaceutical Management System		
Topics	**Achievements**	**Challenges**
Preparing to start	o Trained staff, essential SOPs and forms (bin cards, patient records, medication counselling guidelines), essential infrastructure changes (temperature controlled secure storage space) should be in place before beginning o Ensure the procurement system is prepared	
Implementation	o Follow the plan but be flexible; Don't hurry; Don't underestimate o Be prepared to adapt the plan as necessary o Start when ready and build up numbers slowly but surely o Do not underestimate the level of effort and commitment needed	

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
Collaboration and Partnerships	Proposed changes to strengthen the laboratory services are discussed with CPGH laboratory management and consensus is reached how to move forward	Laboratory sections heads want to be more actively consulted and involved in planning and implementation Technical assistance partners not providing support in procuring reagents other than CD4/CD8 for ART Program
Implementation Planning Process	Process although not easy was successful in reaching consensus and in developing a workplan	Process needs to be more inclusive; laboratory section heads need to be more actively involved Include a site visit to an ART site before developing the implementation plan
Capacity of the Laboratory to Support the ART Program		
1. Program Management and Linkages	ART Program has been integrated into existing laboratory systems so start up was relatively easy. No special registers or systems were needed Formal mechanisms exist to communicate laboratory issues on the ART Program to CPGH management	Many components of the existing system were weak or already stressed by the pressure of the existing workload. Absorptive capacity to support the program as it scales up is rapidly being exhausted Due to staff shortages, laboratory meetings are frequently cancelled and need to be resumed

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
Program Management and Linkages (continued)		Regular interdepartmental forum to address management issues for ART Program needed Unanticipated costs include higher than expected numbers of screening tests, the need for CPGH to absorb all the cost of reagents for testing for Comprehensive Care Clinic (CCC) with the exception of CD4/CD8, and costs related to the identification of co-existing pathologies requiring further investigation
2. Policies and Procedures	ART management guidelines seen to be available at CPGH Laboratory Draft SOPs that build on existing GOK systems and forms developed and tested for CPGH ART Program	Essential reference books have been ordered but not yet received Infrequency of Scientific Meetings holding up approval of SOPs Policy is needed for user fees and exemptions for ART laboratory testing to prepare for arrival of GOK-funded drugs
3. Infrastructure and Equipment	CD4/CD8 technology procured by FHI/IMPACT is in place Filing trays, cabinet and cupboard have improved procedures for sample flow and return of results	Equipment breakdown and lack of automation compounds problems due to staff shortages Essential equipment for haematology and biochemistry needs to be replaced or upgraded Microlitre pipettes and rotors on order are needed urgently Lack of availability of -80 freezer space compromises storage of viral load baseline samples and needs to be addressed

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
4. Human Resources	Monitoring of laboratory workload for ART Program has drawn attention to pre-existing inadequacy of staffing levels and rising workload – is enabling CPGH to justify an increase in staff Laboratory staff are proud to be involved in ART Program; feel that the previous negative image of public hospital laboratory has been improved Multidisciplinary format of initial training contributed to team building and assisted staff in understanding the roles of the different departments Attachment of Port Reitz District Hospital and Bomu Medical Centre laboratory staff to CPGH laboratory extremely useful in preparing them for start up of the program. ART trained laboratory staff feel confident in their skills and capabilities to train others provided that training materials are available	Inadequate staffing levels and rising workload, compounded by lack of automation/ equipment breakdown. CPGH laboratory absorptive capacity is a major constraint to scaling up the ART Program Lack of financial compensation for extra workload from ART Program and working late to finish CD4/CD8 counting is a disincentive Some of the complex joint sessions may need to be reviewed for laboratory staff All CPGH laboratory technologists need to complete the initial training Starting the ongoing training is a priority Additional training on operating the CD4/CD8 machine needed together with training to strengthen computer skills to decrease the time taken in generating the results
5. Specimen Collection, Flow and Return of Results	Specimen collection and flow has been streamlined Improved record keeping system makes it easy to follow CCC and non-CCC samples all the way from collection to dispatch of results Triplicate-copy laboratory request and reporting forms with normal Kenyan values developed	Samples need to reach the laboratory quickly after collection, especially for urea and electrolytes and CD4/CD8 counting Improvements are needed to ensure results are dispatched promptly

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
6. Testing for the ART Program	CPGH laboratory has the capacity to perform HIV diagnosis and a wide range of haematology and clinical chemistry tests including CD4/CD8 counting A facility has been selected to provide viral load testing for the ART Program as needed	Interruptions in service are mainly due to reagent outages and equipment breakdown. The number of CD4/CD8 tests performed each day are restricted due to staff shortages Reagents not routinely kept for lipid profiles or amylase -80 freezer space needed to store the baseline samples for future viral load testing and resistance testing
7. Inventory Management of Reagents and Supplies	Significant improvements in reagent availability have been made but there is still much to do	Periodic shortages of reagents at CPGH still occurring Setting up stock cards, building in lead times, requirements for scale up and performing quality controls into quantification calculations together with increasing buffer stocks are priority needs Reagent budget allocations need to be increased to meet the expanding scale up needs Assistance from USAID-funded technical assistance partners in procuring reagents to support the ART Program requested
8. Quality Control and Good Laboratory Practice	Training and supervision have renewed awareness and improved adherence to the running of daily quality controls (QC) and routine calibration of equipment	Lack of reagents for running internal QC and calibration; budget allocation needs to be increased to include quality control and calibration needs Contractors not always timely in meeting contractual obligations for routine maintenance on equipment. A system to monitor contractor performance is needed

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
Quality Control and Good Laboratory Practice (continued)	Improvements in Good Laboratory Practices include accuracy in record keeping, wearing gloves, setting up an accident and incident record, and developing a PEP protocol for CPGH laboratory	External quality control procedures need to be set up for CPGH; an urgent need is to identify and contract with a facility to provide external quality control for CD4/CD8 counting Staff rarely wear protective coats and goggles due to temperature in non-air conditioned sections
9. Management Information Systems and Monitoring and Evaluation	Record keeping instruments developed and /or adapted from existing forms and registers are working well Triplicate-copy request and reporting forms with normal values for Kenyans, and streamlining of the record keeping system have significantly improved the laboratory management information system Manual record keeping system for ART patients working well for aggregating and analysing results	Draft indicators for tracking laboratory performance and data reporting tools need to be reviewed by CPGH and tested; feedback reports need to be developed Tracking individual patient data for clinical management difficult; computerisation will become a priority as patient numbers increase
Scaling Up		
Needs for scaling up the ART Program at CPGH	o More laboratory technologists are needed immediately to support scale up of the ART Program o Replacement/upgrading of haematology and biochemistry equipment o Increased budget allocation and support from technical assistance partners to purchase reagents o Back up arrangements for clinical chemistry and CD4/CD8 counting o Strengthening supervision to assure quality	
Needs to support roll out to other three sites	o Laboratory capacity of the other three sites is very weak: CPGH laboratory will need to support roll out of the ART Program at least in the short term o In the short term, a system for sample collection and delivery of results o In the long term, automate Port Reitz District Hospital and Bomu Medical Centre with auto analysers for haematology and clinical chemistry	

Six Month Program Review: Laboratory Services		
Topics	**Achievements**	**Challenges**
Lessons Learned and CPGH Recommendations for Other Sites		
Planning	o An implementation plan is essential; there may be many issues to address to strengthen the laboratory and developing a plan collaboratively assists staff in prioritizing issues and sensitises other departments and disciplines to laboratory capacity to start and sustain ART Program o Involve the relevant "on-the-ground" laboratory staff from the beginning so they know what is expected and can contribute to planning o Integrate into existing systems for sustainability – ART is a program not a project	
Preparing to start	o Ensure the laboratory is capable of supporting the ART Program with reliable and timely results during start up and into expansion o Ensure staff are trained and systems are in place to help them to take on the additional workload before starting o Have essential SOPs in place before beginning to assure quality of testing	
Implementation	o Identify a core of well motivated staff o Efficient sample flow and good record keeping are key for ensuring quality of results o Be prepared for costs related to identification of co-existing pathologies requiring further investigation	

The next steps include dissemination of findings and review and update of CPGH implementation plans for the pharmaceutical management system and laboratory based on the findings identified.

Annex 2. Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance November 17 to December 4, 2003

Coast Provincial General Hospital

Update on Pharmacy Implementation Progress – December 4, 2003

Progress to date and next steps are reported for each of the key areas outlined in the CPGH Implementation Plan – developed January 2003.

A. Policies and Standards

1. Guidelines
Progress to date:
The following guidelines are now available in the Pharmacy

- Kenya ARV Therapy Guidelines: 2002 Edition
- Kenya Guidelines For Prevention & Management of Opportunistic Infections and Tumours in HIV/AIDS: 2002 Edition
- Scaling up Antiretroviral Therapy in Resource-limited Settings WHO 2002
- WHO Formulary 2003
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in Paediatric HIV Infection

Next steps:
To assist CPGH Pharmacy to replace guidelines when updated copies are issued.

2. Standard Operating Procedures (SOPs) for the ART Program
Progress to date and Next Steps:

Standard Operating Procedure		Status – December 4, 2003
	Roles and Responsibilities of the CPGH Pharmacy Department in Support of the ART program o Pharmacist in charge of the ART Program o Pharmacist in charge of the ARV bulk store o Pharmacy staff member in charge	All these SOPs have been reviewed by CPGH Pharmacy. All these SOPs were presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee will recommend

Standard Operating Procedure		Status – December 4, 2003
	of dispensing ARVs from the outpatient pharmacy o Pharmacy staff member in charge of preparing prepacks for DAART study o Pharmacist in charge of checking prepacking for DAART study	approval/changes in January 2004. If approved the SOPs will then be presented to the CPGH Management Committee.
102	Receipt of Antiretroviral Drugs at ARV Bulk Store	
103	Record Keeping at ARV Bulk Store	
104	Internal Antiretroviral Drug Distribution	
105	External Antiretroviral Drug Distribution	
106	Record Keeping at the Outpatient Pharmacy	All these SOPs have been reviewed by CPGH Pharmacy. All these SOPs were presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee will recommend approval/changes in January 2004. If approved the SOPs will then be presented to the CPGH Management Committee.
107	Issuing Antiretroviral Drugs to Outpatients	
108	Issuing Antiretroviral Drugs to Inpatients	
201	Shipment Discrepancy Report	
202	Stock Count Discrepancy Report	
302	Medication Error Reporting	
401	Temperature Control	
403	Security of Antiretroviral Drugs	
	CPGH ART Drug Management Flow Charts o Requesting and Receipt of Antiretroviral Drugs o Issuing Antiretroviral Drugs from the ARV Bulk Store Dispensing Antiretroviral Drugs from the Outpatient Pharmacy	

Standard Operating Procedure		Status – December 4, 2003
109	Medication Use Counselling on Antiretroviral Therapy	Has been reviewed by CPGH Pharmacy and information has been harmonised with ICRH and FHI materials. Drug interactions have been added This SOP was presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee will recommend approval/changes in January 2004. If approved the SOP will then be presented to the CPGH Management Committee.
110	Prepacking Antiretroviral Drugs for the DAART Study	SOP has been reviewed and form had an initial test. Final test will be done when DAART study is up and running. This SOP was presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee will recommend approval/ changes in January 2004. If approved the SOPs will then be presented to the CPGH Management Committee.
501	Internal Audit of Antiretroviral Drugs	Is being revised to simplify the form Next step – the SOP and form will be tested by the Quality Committee. SOP and form will be revised and presented to the Scientific Committee for approval in January 2004
502	ART Program: Pharmacy Activity Report	Is being revised to simplify the form Next step – the SOP and report will be tested by the Pharmacy SOP and report will be revised and presented to the Scientific Committee for approval in January 2004
301	Antiretroviral Therapy Adverse Drug Reaction Monitoring and Reporting.	Presented to Scientific Committee on December 4, 2003 for policy decisions. SOP will be revised based on decisions reached and will be tested in December 2003. SOP and report will be revised and presented to the Scientific Committee for approval in January 2004

3. Other Standard Operating Procedures for the Pharmacy

Progress to date: None

Next steps:
RPM Plus will work with CPGH Pharmacy to start drafting other non-ART Program related SOPs in February 2004.

B. Infrastructure/Equipment

Progress to date:
- Lockable cupboards installed in ARV bulk store
- Sliding doors installed to be used as lockable cupboards for DAART prepacks
- Air conditioner installed in ARV bulk store
- Refrigerator purchased for ARV bulk store
- Cupboards grilled for security in outpatient pharmacy
- Booths installed for patient medication use counselling
- Thermometers purchased and temperature monitoring in place for ARV bulk store and refrigerator
- Handed over to CPGH – CPGH providing ongoing maintenance
- Thermometer for outpatient pharmacy was purchased and temperature monitoring set up – temperatures are constantly exceeding the recommended temperature of 25^{O}C. Average temperature in November 29^{O}C.

Next steps
- CPGH to follow up on repairs/poor workmanship
    - Install more secure locks on cupboard in ARV bulk store
    - Stabilise cupboard in ARV bulk store
    - Sliding doors are jammed – plane down doors
    - Adjust locks on the grills of four cupboards in outpatient pharmacy - do not line up and they cannot be locked.
- RPM Plus will discuss options with CPGH to cool the outpatient pharmacy

C. Human Resources - Training

Progress to date:
- 2 pharmacists & 2 pharmaceutical technologists trained in April 2003 – 5 day training
- 1 pharmacist is being trained in the NASCOP training, December 1-5, 2003.
- Topics have been identified by CPGH staff for ongoing training
- Training modules have been developed for Adverse Drug Reaction Monitoring and reporting and Counselling.

Next steps:
- CPGH will provide the venue and organise the logistics.
- Ongoing training will begin January 2004.

- The 5 day initial training is planned in January 2004 – for new staff or staff that missed the initial training

D. Human Resources - Staffing

Progress to date:

- Roles and responsibilities of pharmacy staff for the ART program have been drafted and approved by CPGH Pharmacy staff
- Key responsibilities (e.g. issuing from ARV bulk store and receiving into the outpatient pharmacy) have been separated
- Weekly pharmacy rota identifying staff members to perform key responsibilities has been initiated

Next steps:

- Stabilising staffing levels and increasing participation of a larger number of staff in ARV bulk store management, dispensing and counselling for ART patients and prepacking is key to the success of scaling up the ART Program
- Counselling ART patients can take 30 minutes for first visit and 10-15 minutes for ongoing visits – has implications for staffing as ART Program scales up.
- Organise a catch up workshop for staff who missed initial ART training

E. Stores/Supply Management

Progress to date:

- Record keeping for ARVs as per GOK MOH standard procedures are in place
- RPM Plus is providing technical assistance to CPGH for quantifying requirements
- 3 requests for procurement of ARVs have been submitted to FHI by CPGH
- FHI, RPM Plus and CPGH Pharmacy staff held a second meeting on December 1, 2003 to discuss procurement issues with a particular focus on streamlining the process for ordering supplies, returning stock supplied in error, assuring acceptable shelf life and exchanging short dated stock.

Next steps:

- Develop a quantification methodology
- Train and hand over quantification to CPGH staff – by August 2004

F. Use of ART

1. Prescribing and dispensing

Progress to date:

- Dr Olwande is a member of the Eligibility Committee and acts as Secretary. As a member is quickly able to update Eligibility List and to prepare for new patients
- The following books have been supplied to CPGH Pharmacy

  - AHFS Drug Information (2003)
  - Drugs in Pregnancy and Lactation
  - Martindale: The Complete Drug Reference (2002)
  - British National Formulary (March 2003)
- Pharmacy is now preparing for dispensing for paediatric patients – labels will be printed by ICRH and meetings have been held with Paediatric AIDS Clinic to discuss dispensing issues

Next steps:
- Pharmacy to produce a weekly list of availability of all drugs for CCC to assist prescribing
- Problems with availability of sequentially numbered prescriptions need to be addressed

2. Medication Use Counselling

Progress to date:
- Four staff members have been trained and are available to counsel patients on ART medication – rota provides details of availability and contact information
- SOP has been developed and CPGH/RPM Plus has worked with ICRH/Horizons and FHI to harmonise all information being given out on side effects
- A drug interaction component has been added into the Counselling SOP
- Training materials on Medication Use Counselling for Pharmacy Staff have been drafted

Next steps:
- Pharmacy staff are often being asked about non-medication issues. FHI to prepare standard information for frequently asked questions to assist pharmacy staff
- Pharmacy to work with FHI on developing patient information leaflets on ART
- Produce poster at Window 4 on ART Counselling
- Pharmacy to work on identifying strategies to improve patient flow at Pharmacy booths for non-ART patients to reduce crowding at the hatches.

3. ADR monitoring and reporting system

Progress to date:
- SOP and monitoring and reporting forms have been drafted and revised based on initial input from CPGH pharmacy and medical staff
- Meetings of the Scientific Committee have been postponed to date.
- Training materials on ADR monitoring and reporting have been drafted
- The SOP was presented to Scientific Committee for policy decisions on December 4, 2003.

Next steps:
- Revise SOP and forms based on decisions
- Test forms and SOP
- Revise and finalise training materials based on policy decisions and deliver ADR training
- Submission to Scientific Committee for approval may be delayed until January 2004 to allow adequate time for testing.

4. RDU monitoring and reporting

Progress to date: None

Next steps:

- Begin basic Drug Utilisation Reviews (DUR) in February 2004 as part of six monthly review

5. Dispensing for DAART study

Progress to date:

- SOP and form has been developed and tested
- Responsibilities for preparing prepacks and checking have been split

Next steps:

- As DAART study has only just started and there are few patients to test the system – the SOP and forms need to be retested once the prepacking system is running at full scale
- DAART cupboard in CCC needs to be secured with a bar – ICRH following up
- As many of the ARVs are thermo labile, all DAART storage cupboards should have temperature monitoring – ICRH to follow up

G. Management Information System

Progress to date:

- Manual systems for inventory management and patient profiles have been set up and are up and running smoothly at current work level
- RPM Plus and FHI had a meeting and site visits in October 2003 to identify strategies to improve efficiency in data collection and data quality and reporting for ART Program.

Next steps:

- In January 2004, RPM Plus/FHI will begin to work with CPGH to develop a plan for a unified MIS system for the ART program

H. Monitoring and Evaluation/Performance Improvement

Progress to date:

- SOP and forms for internal audit (internal to CPGH but external to the pharmacy) is being simplified.
- ART Program Activity Report provides information for performance monitoring and also acts as a management tool – provides information on workload and administrative issues that are impacting the ART Program. The SOP and report was tested by the CPGH Pharmacy in September 2003 and is now being simplified.
- In November 2003, the TAP partners worked with CPGH to review progress and performance at six months of the Mombasa ART Program. RPM Plus worked collaboratively with CPGH to identify the areas of interest to be covered in the review and to identify stakeholders to be interviewed. The pharmacy staff and CPGH management were debriefed on the findings.

Next steps:

- Complete and disseminate the results of the six monthly review.

- CPGH to appoint 2 members of the Quality Committee and 1 administrative person to Internal Audit Committee
- Internal Audit Committee to test SOP and forms. SOP and form will be revised and presented to the Scientific Committee for approval in January 2004.
- ART Program Activity Report - SOP and form will be revised and presented to the Scientific Committee for approval in December 2003.

Coast Provincial General Hospital

Update on Laboratory Implementation Progress – December 4, 2003

Progress to date and next steps are reported for each of the key areas outlined in the CPGH Laboratory Implementation Plan which was finalised in August 2003.

A. Policies and Procedures

1. Guidelines

Progress to date:

The following guidelines are now available in the Laboratory

- Kenya ARV Therapy Guidelines: 2002 Edition
- Kenya Guidelines For Prevention & Management of Opportunistic Infections and Tumours in HIV/AIDS: 2002 Edition
- Kenya VCT Guidelines: Latest edition

Next steps:

- To assist CPGH Laboratory to replace guidelines when updated copies are issued.

2. Standard Operating Procedures (SOPs) for the ART Program

Progress to date:

- SOPs have been developed and tested for:
  - Processing Chemistry Specimens
  - Criteria for rejecting chemistry specimens
  - Correcting erroneous reports
  - Alanine aminotransferase analysis by Photometer 5010
  - Aspartate aminotransferase analysis by Photometer 5010
  - γ-Glutamyl Transferase analysis by Photometer 5010
  - Alkaline phosphatase analysis by Photometer 5010
  - Direct bilirubin analysis by Photometer 5010
  - Amylase analysis by Photometer 5010
  - Total bilirubin analysis by Photometer 5010
  - Total protein analysis by Photometer 5010
  - Blood urea analysis by Photometer 5010
  - Creatinine analysis by Photometer 5010
  - Chiron diagnostic 644 Na/K Analyser
  - Complete blood cell count by Coulter Analyser
  - Manual white cell differential count and platelet estimate
  - Sample preparation for CD4 T cell determination by Cytoflow
  - Specimen collection, storage and delivery for viral load testing
  - Sample collection
  - Cell separation: PBMC
  - Post exposure prophylaxis
  - Laboratory Critical/Panic Values
  - Thermometer quality control
  - Refrigerator/freezer maintenance

- The SOPs were presented to the Scientific Committee on December 4, 2003 for review.

Next steps:
- The Scientific Committee will recommend approval/changes in January 2004. If approved the SOP will then be presented to the CPGH Management Committee.
- SOPs to be prepared and tested for
    - Performing CD4 tests
    - Performing cholesterol, triglycerides, LDL, HDL when these tests become available
    - Performing serum lactate and CPK tests when these tests become available at CPGH
    - Record keeping in the laboratory
    - Procurement, storage, inventory management of reagents used in laboratory procedures at CPGH;
- SOPs to be presented to the Scientific Committee for approval in December 2003
- Other laboratory SOPs (not specifically related to ART Program) – development to begin January 2004

B. Infrastructure/Equipment

Progress to date:
- CD4 CyFlow (including an initial supply of reagents and tubes) arrived in October 2003. 4 members of staff have been trained to perform CD4 testing. 108 tests have been performed to date in CPGH laboratory.
- FHI has placed orders for
    - Multichannel pipettes
    - Precision Pipettes

Next steps
- RPM Plus to assist CPGH to provide basic computer training for the 4 staff operating the CD4 CyFlow – lack of computer experience is adding 10 minutes to the testing time for each test,
- The TAP partners to discuss with CPGH on how to secure the machine.
- CPGH had planned to repair the Autolab which would substantially decrease the workload currently involved in using the backup system. However, it has been found that the Autolab is not repairable. The next step is to identify options on how to proceed.
- FHI to order rotor for CCC to prevent blood samples from clotting
- Monitor need for other equipment/upgrades as program scales up

Human Resources – Training

Progress to date:
- 4 lab technologists trained in April 2003 – 5 day training
- Topics have been identified by CPGH staff for ongoing training
- List of key books/reference materials have been identified

Next steps:
- CPGH will provide the venue and organise the logistics.
- Ongoing training will begin January 2004.
- The 5 day initial training is planned in January 2004 – for new staff or staff that missed the initial training

C. Human Resources – Staffing

Progress to date:
- Roles and responsibilities of ART Program Laboratory Coordinator have been developed by CPGH. Dr Denje, laboratory supervisor has been identified to take on the duties initially

Next steps:
- Review additional workload 3 monthly and develop plan for long term

D. Blood Specimen Collection

Progress to date:
- Register has been set up in the outpatient department (OPD) to record all patients bled and samples collected
- Regular collection service has been established to bring samples from OPD to the main lab and return results to CCC
- Lab request forms and reporting forms have been drafted and are being tested by CCC
- Registers have been established in each section of lab

Next steps:
- Improve labelling of samples

E. Testing

1. HIV Diagnosis

Next steps:
- Shortages of HIV rapid kits and ELISA reagents are impacting the program and need to be followed up on

2. Haematology and Clinical Chemistry

Next steps:
- Shortages of haematology and clinical reagents are impacting the program and need to be followed up on. RPM Plus to assist in strengthening inventory management information system in January 2004.
- Purchase calibration reagents and institutionalise calibration

CD4
Progress to date:
- CD4 CyFlow (including an initial supply of reagents and tubes) arrived in October 2003. 4 members of staff have been trained to perform CD4 testing. 108 tests have been performed to date in CPGH laboratory.
- RPM Plus is assisting CPGH to identify and institute to provide external quality control for the CD4 CyFlow.

Next steps
- RPM Plus to assist CPGH to provide basic computer training for the 4 staff operating the CD4 CyFlow – lack of computer experience is adding 10 minutes to the testing time for each test,
- The TAP partners to discuss with CPGH on how to secure the machine.

3. Viral Load
Progress to date:
- Baseline samples are not being collected and stored for possible future testing due to the lack of -80 freezer storage space
- Survey to identity appropriate facility has been performed. KEMRI has been identified for an initial 3 month contract – to continue based on performance
- FHI/RPM Plus have visited KEMRI to discuss contract and preparation of samples for testing.

Next steps:
- CPGH/FHI to identify -80 freezer storage for samples
- FHI to set up viral load testing at KEMRI
- RPM Plus to develop SOP for preparing and transporting samples for viral load testing

4. Viral Resistance Testing
Progress to date:
- Baseline samples are not being collected and stored for possible future testing due to the lack of -80 freezer storage space

Next steps:
- CPGH/FHI to identify -80 freezer storage for samples
- RPM Plus to follow up to monitor process

F. MIS

Progress to date:

- Lab request and reporting forms have been drafted and are currently being tested
- RPM Plus and FHI had a meeting and site visits in October 2003 to identify strategies to improve efficiency in data collection and data quality and reporting for ART Program.

Next steps:
- In February 2004, RPM Plus/FHI will begin to work with CPGH to develop a plan for the MIS system for the ART program

G. Good Laboratory Practice

Progress to date:
- An accident/incident register has been set up
- SOP for PEP has been developed

Next steps:
- Develop training materials to promote Good Laboratory Practice in CPGH Laboratory.

H. Monitoring and Evaluation/Quality Control

Progress to date:
- In November 2003, the TAP partners worked with CPGH to review progress and performance at six months of the Mombasa ART Program. RPM Plus worked collaboratively with CPGH to identify the areas of interest to be covered in the review and to identify stakeholders to be interviewed. The Chief Pathologist and CPGH management were debriefed on the findings.

Next steps:
- Debrief the laboratory staff in January 2004 on findings of six monthly review when staff return from vacation.
- Complete and disseminate the results of the six monthly review.
- Develop a plan to strengthen QA/QC in lab

I. Financing

Next steps:
- Need to develop a policy for non-ART Program patients seeking CD4 testing at CPGH
- Need to determine whether patients being retested for HIV as screening for the ART program will be charged a fee

Implementation at Port Reitz District Hospital, Bomu Medical Centre and Magongo Clinic

Update on Pharmacy and Laboratory Implementation Progress

A. Port Reitz District Hospital

Progress to date

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training
- FHI and RPM Plus met with Port Reitz District Hospital staff in October 2003 to draft implementation plans for introduction of ART for service delivery, pharmacy and laboratory.

Next steps

- Implementation is pending approval of the plan by Port Reitz District Hospital Management.
- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- Ongoing training will begin January 2004.
- A repeat of the 5 day initial training is planned for January 2004 – for new staff or staff that missed the initial training
- Port Reitz District Hospital staff will commence partnering assignments with CPGH in December 2003. Medical staff will work with Dr Otieno, nursing staff with CCC staff, pharmacy staff with Dr Olwande and laboratory staff with Mr Denje.

B. Bomu Medical Centre

Progress to date

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training
- Two follow on visits to the laboratory were made in July/August 2003.
    - No new equipment has yet been purchased and donors are still to be identified. (Bomu Medical Centre are requesting donations of a colorimeter and Autolab)

Next steps

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- FHI and RPM Plus will meet with Bomu Medical Centre staff in January 2004 to develop implementation plan for introduction of ART
- Ongoing training will begin January 2004.
- A repeat of the 5 day initial training is planned for January 2004 – for new staff or staff that missed the initial training
- Bomu Medical Centre staff will commence partnering assignments with CPGH in December 2003. Medical staff will work with Dr Otieno, nursing staff with CCC staff, pharmacy staff with Dr Olwande and laboratory staff with Mr Denje.

C. Magongo Municipal Clinic

Progress to date

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training – however, since then , the trained staff at Magongo have been transferred
- Municipal Council – health officer have all been replaced. FHI and RPM Plus met with the Medical Officer for Health (Dr Chidagaya) and Deputy (Dr Were) to brief them on the ART Program.
- New Sister at Magongo has been briefed on the ART program and provided with a copy of al assessment results
- Two follow on visits to the laboratory were made in July/August 2003.

Next steps

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- Ongoing training will begin January 2004.
- A repeat of the 5 day initial training is planned for January 2004 – for new staff or staff that missed the initial training

List of activities November 15 to December 5, 2003

November 17 Monday
Meet with RPM Plus staff to review CPGH lab implementation plan
Meet with RPM Plus staff to plan for six monthly review

November 18 Tuesday
Dr Mwangi – courtesy visit; objectives of visit
Dr Baya – courtesy visit, objectives of visit
Dr Denje – courtesy visit and update, objectives of visit
Meeting with training officer to plan for ongoing training
RPM Plus meeting to plan for six monthly review

November 19 Wednesday
Dr Mwangi – planning for six monthly review; updates
Dr Baya, Dr Nzumba, Dr Kimatu – planning for six monthly review; updates
Dr Nzumba – follow up on pharmacy issues, data for quantification; ART expiry chart
Meeting with Dr Otieno – update in pharmacy & lab issues
ICRH – meeting with ICRH/Horizons staff to plan for six monthly review, updates on DAART study, MIS

November 20 Thursday
Mr Denje and Dr Mandaliyia – objectives of visit; planning for six monthly review; follow up on updates
CPGH Eligibility Committee meeting
Meeting with Dr Olwande & Dr Majimbo – planning for six monthly review

November 21 Friday
Instruments developed

November 24
Interview Dr Baya – six month review
Meeting Dr Achola to discuss testing of internal audit SOP
Meeting with TAP partners to discuss laboratory issues

November 25 Tuesday
Meeting with Mr Denje – six month review
Meeting with Dr Nzumba – six month review
Meeting with Mr Mwamburi – six month review
Meeting with Dr Olwande – six month review

November 26 Wednesday
Data collection at CPGH Lab for six monthly review

November 27 Thursday
Meeting with CPGH lab techs – six month review
Meeting with Dr Kimatu – six month review
Meeting with Khadijah – six month review
Meeting with Bomu Medical Centre – six month review and planning for implementation

November 28 Friday
Meeting with Dr Mwangi - six month review
Port Reitz District Hospital - six month review and follow up on implementation plan
Meeting with Dr Mandaliyia - six month review

December 1, 2003 Monday
Procurement of ARVs meeting – TAP partners

December 3, 2003 Wednesday
Pharmacy debriefing of six monthly review

December 4, 2003 Thursday
Debriefing of CPGH Management on six monthly review
Scientific Committee meeting

December 5, 2003 Friday
Debriefing at USAID/Kenya